Teleconference

Hat is your question -- and would you like to ask it live on the air or would you prefer that we write it down?

QUESTION

You refer to days in computing
The appeals process timeline,
does this mean calendar days
or working days?

Now I'm going to put you on hold. While on hold, you'll be able to hear the program in progress. When you hear the moderator announce your line number, turn down your TV set and ask your question.

02N-0275

LST 1

U.S. Food and Drug Administration Southwest Imports District 4040 N. Central Expy., Suite 300 Dallas, Texas 73204

(214) 253-5330 Fax (214) 253-5317





Fax: 888-361-4011 From: (optional)

Re: Public Meeting on BT proposed regs Date: 5/7/03

• Question:

If administrative defeation is issued for a single article of food on an import vessel (truck, plane, ch.) with multiple articles, are all articles on that vessel held or only the single article in question

High Priority - Steve

The Bioterrorism Act immediately
gave FDA its detention outhority. Has
FDA used this authority to date?

High Privary Lestye

Public Meeting via Satellite Downlink - May 7, 2003

RECORDKEEPING AND ADMINISTRATIVE DETENTION PROPOSED RULES

Fax Question Sheet

	Please print clearly in the space below	
	for minon failured to file sprion	
	Tapa asi o	
	Will the administrative	
	detention authority be used	
\	to detain food for which	
	no prior notice was submitted	1;
\		

If a product is detained for a period of time in which the product is no longer fit for consumption, then gets released, what responsibility falls on FDA?

At the bothers, what are secure starage" facilities"?

Does FDA have warehouses? Will FDA use Customs' facilities for Storage of detained Goods?

Steve

CDRH Teleconference Questions

From: Sent:

To:

SCHILLING@AESOP.RUTGERS.EDU Wednesday, May 07, 2003 2:26 PM TVQUESTION@CDRH.FDA.GOV

How does the FDA plan to draw a distinction between an order of detention for a suspected act of bioterrorism and a historically more routine reason (ie plant or supplier indirect accidetn/adulteration)?

Steve,

Has FDA considered the economic impact of this proposal?



US FOOD & DRUG ADMINISTRATION NYK-DO ALBANY RESIDENT POST ONE WINNERS CIRCLE, SUITE 110 ALBANY, NEW YORK 12205-5974

PHONE: 518-453-2314 518-453-2443 FAX:



Bioterrorism Dour link

Fax: Pages: / Phone: 518-453-33,4 Date: Re: CG: COUR ONly	• Comment	s:				
Fax: Pages: / Phone: 518 - 453 - 2314 Date:	□ Urgent	☐ For Review	☐ Please Co	mment	☐ Please Reply	Please Recycle
Fax: Pages: /	Re:	· · · · · · · · · · · · · · · · · · ·		CC:	COVER	only
	Phone: 51	8-453 2314	, 	Date:		
To: 1-888-361-4011 From:	Fax:			Pages:		
	To: / -	888 -361	1-4011	from:		

Can the administrative detention or other provisions of the BT regulations be used for non-terrorist confaminations such as

insect, bacterial, chemical?



Could extendating circumstances
ever exist to justify the immediate

Scizure & destruction of an article

without receipt of an order or

detention?

9901 S. Cage Boulevard, Suite B Pharr, TX 78577 Phone: 955-283-2190 or 283-2191 Fax: 956-283-2192

UNITED STATES FOOD & DRUG ADMINISTRATION



Fax

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• Comments:

IF an importer or customs Broker Imports Food on weekends and that Food gets transported to another Location Not IN the the original Bistrict H WAS Imported through. IF F.D.A. Wants to see it can the shipment be top inspected by another F.D.A. Distorphent to preferred to original Disti

Public Meeting via Satellite Downlink -- May 7, 2003

RECORDKEEPING AND ADMINISTRATIVE DETENTION PROPOSED RULES

Fax Question Sheet

Please print clearly in the space below

·	
100	Upon what legal authority are you selving to regulate foods that are not in interstate.
	to regulate foods that are not in interstate.
	Commerce:
	•
	·

Lesty

DO1

14:25

Food and Drug Administration

5600 Fishers Lane, Room 14-90, HFC-01 Rockville, Maryland 20857 Phone: (301) 827-3101 FAX: (301) 443-6591

ORA



TO: Bob Lake/Lesye Frasci

FAX #:

FROM: Clint Chamberlin

DATE. 5/7

No. of pages (including cover): /

COMMENTS

when is the effective date for administrative detendion ruling?

This document is intended for the use of the party to whom it was addressed and may contain information that is privileged, confidential, and protected from disclosure under applicable law. If you are not the adoressee, or the person authorized to deliver the document to the addressee, you are hereby notified that any reviaw, disclosure, dissemination, or other action based on the content of this communication is not authorized. If you have received this document in error, please notify us by telephone at (301) 827-3101 and return it to the above address by mall. Thank you.

STATE

High Printy !

Teleconference

lesty

What is your question -- and would you like to ask it live on the air or would you prefer that we write it down?

QUESTION

don refer to days in the appeals timeline, does that mean working days or calendar days?

Now I'm going to put you on hold. While on hold, you'll be able to hear the program in progress. When you hear the moderator announce your line number, turn down your TV set and ask your question.

are pet foods exempt as they are in the record keeping regulation

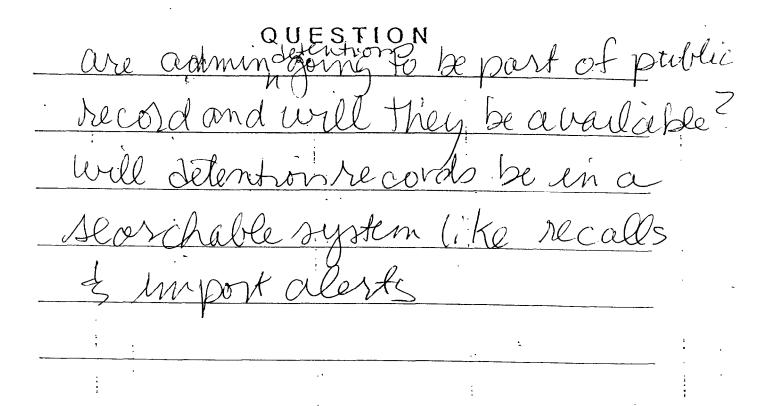
What information would be available to an owner of food product concerning testing of the product during the detention period?

town Hach

CA

Teleconference

What is your question -- and would you like to ask it live on the air or would you prefer that we write it down?



Now I'm going to put you on hold. While on hold, you'll be able to hear the program in progress. When you hear the moderator announce your line number, turn down your TV set and ask your question.

Steve

Can you explain
the difference between
an import detention
and an administrative
detention?

LINE NUMBER IS STATE
priority
Teleconference (2
ADMINISTRATIVE Detention
What is your question and would you like to ask it
live on the air or would you prefer that we write it
down? From: Chilean Salmon Growers
ASSOCIATION - (3 questions
It's not clear in the Act who
will assume the cost of storage
and protection of the Food. This
is especially important because
foods can be detained for up to
Foods can be detained for up to 20 or 30 days.
Cilil ilic not clear who
Similarly ITS No. O.Car
WITH PAY THE COSTS OF TABELLING
Similarly, it's not clear who will pay the costs of labelling or marking the article of food. Who bears these costs?
Now I'm going to put you on hold. While on hold, you'll
be able to hear the program in progress. When you hear
the moderator announce your line number, turn down or your TV set and ask your question.
J.

LINE NUMBER IS STATE HIGH
Teleconference Priouts
What is your question and would you like to ask it live on the air or would you prefer that we write it down? Administrative Determinant
From: Chilean Growers Association
Does the Act address procedures For reparation if *basis for the detention is proved to be groundless We are concerned about both
monetary losses and the reputation of the company (3) What measures will be put conomic live place to minimize the damage, liability of the damage, liability of the damage.
Now I'm going to put you on hold. While on hold, you'll be able to hear the program in progress. When you hear the moderator announce your line number, turn down your TV set and ask your question. Ay state or reputation of a Specific producer, product, or even a country because was detained. Will detentions be Kept Secret.

LINE NUMBER IS STATE
Teleconference Alministrative Desention What is your question and would you like to ask it live on the air or would you prefer that we write it down? Chilean Salman Growens Association
QUESTION
1 What is the plan to enact these regulations? 2 What does an 'article of food'
mean? Does that mean a sample a unit in a shipment, the whole container, or the whole shipment?
(3) Have you considered that the
Now I'm going to put you on hold. While on hold, you'll be able to hear the program in progress. When you hear the moderator announce your line number, turn down your TV set and ask your question. of a perishable fook may result in its elimination from the market? Please review the special provisions for perishable food.

Public Meeting via Satellite Downlink - May 7, 2003

RECORDKEEPING AND ADMINISTRATIVE DETENTION PROPOSED RULES

Fax Question Sheet

Please print clearly in the space below	
Does the detention	
proposal apply to	
food contact materials	
1. C. substances that migrate france packaging	 >
to food.	

STATE

Teleconference

What is your question -- and would you like to ask it live on the air or would you prefer that we write it down?

I what info would be avail to.
owener of food prod concerning
testing of prod during dentitating
(6) would tab ripte be provided?
3) Could town manche status of the
teresone accels? day period, ie
tellesonone accessi

Now I'm going to put you on hold. While on hold, you'll be able to hear the program in progress. When you hear the moderator announce your line number, turn down your TV set and ask your question.

U.S. Food & Drug Administration New York District Office **Import Operations Branch** 158-15 Liberty Avenue Jamaica, NY 11433



FAX COVER SHEET

From:	
Voice: (718) 340-7000 ext	
Fax: (718) 662-5662 or (718) 662-5663
То:	
Phone:	Fax:
Date: For imported food, Willyou ever ask to me imported location paid So, how will the mo	Page 1 of ove detained food from its origina; or to Customs release? And it

ت الما ما معادي الدائل المعاد و و مستقد القائل الموسمة على والراب المواريين الما الروائدي و الروائد الروائد

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Date:

Operator:

Cover +

MESSAGE:

Down In Overtion

How does the 30 day detention

relate to the former 180 day

redelivery rule.

ROBER & MART, Director

Into: Operator:

ROBER & MART, DIRECTOR

ROBER & MART, DIRECTO

Teleconference

What is your question -- and would you like to ask it live on the air or would you prefer that we write it down?

QUESTION

Protection be used to request swould entail add I penalties for faiture to comple):
What form will the Seizure order take?
Who will issue it? What will be the appearance Now I'm going to put you on hold. While on hold, you'll be able to hear the program in program.

the moderator announce your-line number, turn down * your TV set and ask your question. ofy state

Public Meeting via Satellite Downlink -- May 7, 2003 RECORDKEEPING AND ADMINISTRATIVE DETENTION PROPOSED RULES

Fax Question Sheet

Please print clearly in the space below

BULK SHIPMENTS OF FOOD CARGO TANK TRAILERS SEALED AS OFTEN ARE MEASURE IF THE FDA DETAINED BROKE THE SEALS TRUCK AND INSPECTION PURPOSES, WOULD PUT INTO PLACE THAT WOULD AN OFFICIAL GOVERNMENT GENERATE DOCUMENT DETAILING ME OFFICIAL BROKE THE SEAL AND WHO RESEALED

Sul C

Public Meeting via Satellite Downlink -- May 7, 2003

RECORDKEEPING AND ADMINISTRATIVE DETENTION PROPOSED RULES

Fax Question Sheet

Are substances that migrat from packaging to tood covered by the proposed regulation.	covered by the proposed	covered by the proposed	covered by the proposeo
regulation.	regulation.	regulation.	regulation.

CDRH Teleconference Questions

From:

Sent: To:

Kate Chilton [chillybean5@hotmail.com] Wednesday, May 07, 2003 2:50 PM TVQUESTION@CDRH.FDA.GOV BT QUESTION PLATTSBURGH NY LOCATION

Subject:

702B PORTIONS NOW APPLY TO IMPORTED PRODUCTS?

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CDRH Teleconference Questions

From: Kate Chilton [chillybean5@hotmail.com]
Sent: Wednesday, May 07, 2003 2:45 PM
TYOUESTION@CDBH EDA COV

To: TVQUESTION@CDRH.FDA.GOV
Subject: BT QUESTION PLATTSBURGH NY LOCATION

IS FDA PLANING ADDITIONAL 24/7 IMPORT COVERAGE IN ORDER TO FACILITATE EXPEDITIOUS ENFORCEMENT OF ALL THE PROPOSED REGULATIONS?

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From:

CDRH Teleconference Questions

From: Sent:

Manney, Richard D

To:

Wednesday, May 07, 2003 2:44 PM **CDRH Teleconference Questions**

Re: Admin. Detention

- 1. Will there be a pre-approved/ pre-printed form that will need to be completed by the Districts with the required information?
- 2. After approval by the DD- Does the order go directly to the firm- or first through either OCC or an AUSA?

Richard D. Manney Compliance Officer **USFDA- New Jersey District**

Ph: 973.526.6008

Internal FDA proceedures



Public Meeting via Satellite Downlink -- May 7, 2003

RECORDKEEPING AND ADMINISTRATIVE DETENTION PROPOSED RULES

Fax Question Sheet

V	Please print clearly in the space below
	If perishable food detained by the FPA is turned out harmless
D)//	and it the food is
	during Metantion period;
	Will it be componsated

LINE NUMBER IS		STATE	Joan
Tel	econfe	rence	Atlanta, GA
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Now I'm going to put you on hold. While on hold, you'll be able to hear the program in progress. When you hear the moderator announce your line number, turn down your TV set and ask your question.

Teleconference

What is your question -- and would you like to ask it live on the air or would you prefer that we write it down?

QUESTION

Instead of gen'l statement about why comment is product is defained would want a specific reason to see if reason is valid,

Now I'm going to put you on hold. While on hold, you'll be able to hear the program in progress. When you hear the moderator announce your line number, turn down your TV set and ask your question.

Zachary R. Freedman, M.D., F.A.C.E.
Division of Endocrinology
Director, Diabetes Care & Resource Center

Robert James Bingham, M.D., F.A.C.E.

Phone: 585-922-8400 Fax: 585-922-8405

Division of Endocrinology
Diabetes Care & Resource Center
Nutrition/Weight Management Center

ViaHealth 222 Alexander Street Suite 5500 Rochester, NY 14607

Fax

	To:	FDA	Fı	rom:	Dr. 200	neo	Bingh	ian
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thanko! Finda &M

CDRH Teleconference Questions

From: Sent: Kate Chilton [chillybean5@hotmail.com] Wednesday, May 07, 2003 2:25 PM

To: Subject:

TVQUESTION@CDRH.FDA.GOV BT QUESTION PLATTSBURGH NY LOCATION

1) who is resonsible for transferring detained product to a secure storage
facilility?

the shipper importer or FDA?

2) who chooses the transporter to transfer detained product to a secure storage facility? is it an fda approved carrieror shippers choice?

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Who is responsible for transferring detained product to a secure storage facility - the shipper, importer, or FDA?

Who etwoses the transporter to transfer detained product to a secure storage faculty is it an FDA-approved carrier or the shippers charge U.S. Food and Drug Administration Southwest Imports District 4040 N Central Expy., Suite 300 Dallas, Yexas 75204

(214) 253-5330 Fax (214) 253-5317



Fax:	888-361-4011	From:		(optional)
Re:	Public Meeting on BT proposed regs	Date:	5/7/ 03	

Question:

We have a product that has a 30 day shalflife.

it vader goes "high Pressure" Cold Pasturation. How

can we change our product to A perishable. Food? A 30 day detention means the product
is out of Date + next to the Currently means we are stock with, it



DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION

TOPIC:

RECORD KEEPING AND ADMINISTRATIVE DETENTION PROPOSED RULES

(OF THE)

BIOTERRORISM PREPAREDNES AND RESPONSE ACT OF 2002

FAX FORM

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For the	Adulter	ATION	
((OPTIONAL) SUBMITTED BY:	FLOCIDA	DISTRICT	STATE:

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Public Meeting via Satellite Downlink -- May 7, 2003

RECORDKEEPING AND ADMINISTRATIVE DETENTION PROPOSED RULES

Fax Question Sheet

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SAMPLE NAME	25	B

BEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION

Survey pranjours

TOPIC:

RECORD KEEPING AND ADMINISTRATIVE DETENTION PROPOSED RULES

(OF THE)

BIOTERRORISM PREPAREDNES AND RESPONSE ACT OF 2002

FAX FORM

QUESTION IN the case of A Cistans broker where	
does their linkity and lake contenting for the inventor	
I delivery of the primit to their exsterner?	
	•
((OPTIONAL) SUBMITTED BY:	

U.S. Food and Drug Administration Southwest Imports District 4040 N. Central Expy., Suite 300 Dallas, Texas 75204

(214) 253-5330 Fax (214) 253-5317







(optional) From: 888-361-4011 Fax: Date: 5/7/03 Public Meeting on BT proposed regs Re:

CAN YOU Appeal and Import Detention? }
What is the time table For the Appeal?

Is it the Same 5 Days?

U.S. Food & Drug Administration 6751 Steger Drive Cincinnati, OH 45237 Phone: 513-679-2700

Fax: 513-679-2771

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Cincinnati. OH 45237 Phone: 513-679-2700 Fax: 513-679-2771

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Public Meeting via Satellite Downlink -- May 7, 2003 RECORDKEEPING AND ADMINISTRATIVE DETENTION PROPOSED RULES

Fax Question Sheet

11:-

Public Meeting via Satellite Downlink -- May 7, 2003

RECORDKEEPING AND ADMINISTRATIVE DETENTION PROPOSED RULES

Fax Question Sheet

	Please print clearly in the space below
_	Timely Lab analysis have been very deficult to get, will FDA improve the timelinus by contraction with more labs? Also since more analysis' will be
newered	If a detention order is issued for a perishable, tood, but no seizure action, does the 30 day detention period apply? What can the owner of the product do to get the product released.

Public Meeting via Satellite Downlink -- May 7, 2003

RECORDKEEPING AND ADMINISTRATIVE DETENTION PROPOSED RULES

Fax Question Sheet

The mosted food consigned is
Approprise to wing the
If an imported tood consignment is detained under the Act does FDD propose to notify the exporting country.

Public Meeting via Satellite Downlink -- May 7, 2003 RECORDKEEPING AND ADMINISTRATIVE DETENTION PROPOSED RULES

Fax Question Sheet

V M(Please print clearly in the space below
a marin	WILL FOR GO BACK ON CUSTOMS IMPORTER OF RECORD
	FOR PENALTY ACTION - DANGENGE

7.7.

Public Meeting via Satellite Downlink -- May 7, 2003 RECORDKEEPING AND ADMINISTRATIVE DETENTION PROPOSED RULES

Fax Question Sheet

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9901 S. Cage Boulevard, Suite B Phart, TX 78577 Phone: 956-263-2190 or 283-2191 Fax: 956-263-2192

UNITED STATES FOOD & DRUG ADMINISTRATION

Fax

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	Conjuen	icotor / Do	cement	15 Perus C	

5- 7-03;11:25AM; [MPACT Center____,

Can the FDA exercise this authority for any Reason or must the detention be related to a suspected tennenist act?

Who is Rosponsible for paying for storage and transportation of a detained product?

Public Meeting via Satellite Downlink -- May 7, 2003

RECORDKEEPING AND ADMINISTRATIVE DETENTION PROPOSED RULES

Fax Question Sheet

M3ecure StorAGE FACILITIES?
"Secure STORAGE FACILITIES"!
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WILL SHIPPERS CARRIERS OF
mporters Br charged for This prorage?
This prorage?
WAREHOUSES? WILL FOR USE CUSTOMS HACILITICO?
WAREHOUSES?
with FDAUSE CUSTOMS HACILITIES!
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Public Meeting via Satellite Downlink -- May 7, 2003

RECORDKEEPING AND ADMINISTRATIVE DETENTION PROPOSED RULES

Fax Question Sheet

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DETENT	ion w	DER F	DA?	